K131248

510(k) Summary

Date: July 11, 2013 JUL 1 1 2013

Owner's Name:
Address:
DMG America, LLC
242 South Dean Street
Englewood, NJ 07631
(201) 894-5500

Contact Person:
Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432
(978) 772-3552

Subject Device:
Trade Name: Etch Gel
Common Name: Dental etching gel
Classification Name: Resin Bonding Agent
(21 CFR 872.3200, Product Code KLE; Class II)

Predicate Device:
Trade Name: Zenith 40% Phosphoric Acid Gel (Foremost Dental Mfg, Inc.)
Common Name: Dental etching gel
Classification Name: Sealant, Pit and Fissure, and Conditioner
(21 CFR 872.3765, Product Code EBF; Class II)
Premarket Notification: K890464

Product Description:
The device described in this 510(k) consists of a water-based gel containing 40% phosphoric acid.

Indications for Use
Preparation of tooth material prior to restoration by etching of the surface.

Substantial Equivalence
Substantial Equivalence for the DMG America, LLC Etch Gel is based upon comparison to the physical properties, material composition, description of product packaging/delivery mechanism and indications for use of the predicate device. Technological characteristics and non-clinical performance data provided in this 510(k) consist of chemical composition, description of product packaging/delivery mechanism, and physical properties measurements (pH, viscosity and specific gravity). The Etch Gel is either the same as or equivalent to the predicate device in terms of these technological characteristics and non-clinical performance data.

Conclusion:
The Etch Gel has been shown to be substantially equivalent in safety and effectiveness to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 11, 2013

DMG America, LLC
C/O Ms. Pamela Papineau, RAC
Delphi Medical Device Consulting, Inc.
5 Whitcomb Avenue
Ayer, MA 01432

Re: K131248
Trade/Device Name: Etch Gel
Regulation Number: 21 CFR 872.3200
Regulation Name: Resin Tooth Bonding Agent
Regulatory Class: II
Product Code: KLE
Dated: February 20, 2013
Received: May 01, 2013

Dear Ms. Papineau:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mary S. Runner -S

Kwame Ulmer M.S.
Acting Division Director
Division of Anesthesiology, General Hospital,
Respiratory, Infection Control and
Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 4 – Indications for Use Statement

510(k) Number (if known): K131248

Device Name: Etch Gel

Indications for Use:
Preparation of tooth material prior to restoration by etching of the surface.

Prescription Use X OR Over-the -Counter Use ____
(Per 21 CFR 801 Subpart D) (Per 21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Susan Runner -S
DDS mA 2013.07.11
15:06:33 -04'00'

(Division Sign-Off)
Division of Anesthesiology, General Hospital Infection Control, Dental Devices

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